

# EXHIBIT 11

**EXPERT REPORT OF DR. BRIAN REISSETTER**

**I. BACKGROUND, EXPERIENCE, AND QUALIFICATIONS**

1. My name is Dr. Brian Charles Reisetter. I am submitting this report at the request of Abbott Laboratories Inc. in the lawsuit titled *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc.*, Case No. 07-CV-11618.
2. I graduated in 1985 with a Bachelor of Science (BS) degree in Pharmacy at Drake University in Des Moines, IA. I graduated from Drake University in 1987 with a Master of Business Administration (MBA). I completed extensive graduate work at the University of Illinois at Chicago (UIC) in the Doctor of Philosophy (PhD) program from 1993 until 2000. The emphasis of this graduate work was social science and communication as they relate to the profession of pharmacy.
3. In 2002, I graduated from the University of Mississippi with a Doctor of Philosophy (PhD) in Pharmacy Administration with an emphasis in Pharmaceutical Marketing.
4. In conjunction with my graduate academic work, I was a teaching assistant at both the University of Illinois at Chicago and the University of Mississippi in several courses, including Pharmacy Law and Pharmacy Communications.
5. I am currently an Adjunct Professor for the University of Mississippi, College of Pharmacy where I have taught one course entitled The Techniques of Pharmaceutical Sales. I taught this course for six consecutive years.
6. I am also an appointed member of the National Advisory Board for the Drake University College of Pharmacy and Health Sciences. I am currently serving my second three-year term in this capacity.
7. I have been licensed as a pharmacist in the State of Iowa since 1985. I was also licensed to practice pharmacy in the State of Illinois from 1992 until 2000. I am currently licensed as a pharmacist in the State of Mississippi.
8. Since licensed in 1985, I have practiced pharmacy full-time (1985-1987, 1992-1998) and part-time (1998-2000) in retail pharmacy (chain and independent) and in hospital pharmacy (inpatient and outpatient) in the states of Illinois and Iowa. I have worked in approximately 15 to 20 different retail pharmacies. As a retail pharmacist, my duties included purchasing and claims submissions to public and private third party payers of drugs, including Medicaid, for the stores where I was contracted or employed.
9. I was a professional sales representative for Eli Lilly and Co., Inc., from 1987 until 1992. My territory was based out of Des Moines, IA.

10. I served as Director of Pharmacy at Chicago Lakeshore Hospital Pharmacy in Chicago, IL, from 1992 until 1998 in conjunction with my previous corporation, Reisetter Pharmacy Health Services, Inc. (RPHS). During that time, I was fully responsible for prescription and non-prescription pharmaceutical product purchasing for the hospital. I was also a member of the Pharmacy and Therapeutics (P&T) Committee and the Risk Management Committee as part of my normal duties.
11. Through RPHS, I have consulted for several clients regarding marketing issues in the pharmaceutical industry. RPHS was active as a corporation from 1993 through 2001.
12. I was a contracted "relief" pharmacist in both Illinois and Iowa through RPHS for independent and chain pharmacies needing pharmacists for limited amounts of time. I would often manage or operate independent pharmacies for the owners while they were sick or on vacation. My activities in this role included product purchasing and claims submission for all prescriptions dispensed.
13. I am a founding partner of Medical Marketing Economics, LLC (MME), where we work extensively with the pharmaceutical industry in the areas of pricing, marketing strategy and market research. MME also provides limited litigation support and expert witness testimony.
14. Through my education, research, professional experiences in the pharmaceutical industry and in the practice of pharmacy, and my work with MME, I have extensive knowledge of pharmaceutical marketing and promotion.
15. My experience, publications, and prior testimony are provided in detail in my CV.
16. Medical Marketing Economics (MME) is being compensated at a rate of \$450 per hour for my work in this matter.

## **II. TASKS REQUESTED**

17. I have been asked to testify on the following subject matters:
  - a. The methodology used by Dr. Matthew Perri to support his opinions in this lawsuit and whether that methodology is scientifically valid and can yield reliable and valid conclusions.
  - b. How pharmaceutical companies market their products, specifically:
    - i. How companies develop an overall marketing strategy for their products, and how those strategies are implemented.
    - ii. The frequency and modes of communication companies use to implement an overall marketing strategy for a product, both to

internal members of the company and to the market participants (e.g., customers).

- c. How any strategy to market the difference between acquisition cost and the government payment amount (“the spread”) for products would be implemented, and what sources of evidence would exist if such a strategy were designed and implemented.
  - d. Regardless of the methodology employed, whether Dr. Perri’s opinions are supported by evidence, whether Dr. Perri ignored or discounted evidence that contradicts his opinions, and whether his opinions are consistent with certain market realities.
18. To complete this task, I relied upon my education, knowledge, experience, and a review of the materials that are provided in the attached schedule.

### **III. SUMMARY OF OPINIONS**

19. My general opinions in this matter are as follows:
- a. Dr. Perri did not use any scientifically valid methodology to form his opinions in this case. The “descriptive/explanatory case study” that he describes in his report is not a scientifically valid methodology that is designed to or capable of yielding the types of conclusions that Dr. Perri presents.
  - b. Dr. Perri’s subjective opinion that Abbott “marketed and enabled the marketing of the reimbursement spread to its customers” with respect to its Erythromycin (“Ery”) products is not supported by the evidence he cites in his report. The evidence cited in Dr. Perri’s report could not constitute a corporate marketing plan or strategy to market the Ery products based on the spread.
  - c. Dr. Perri cites no evidence to support certain statements in his report, and he ignores substantial evidence that contradicts his subjective opinion that Abbott marketed its Ery products based on the spread.
  - d. Dr. Perri’s subjective opinion that Abbott marketed the spread for its Ery products is inconsistent with market realities, such as the fact that uniform payment capitations including a Federal Upper Limit (“FUL”) or Maximum Allowable Cost (“MAC”) were in place for Ery products for most of the time since 1994.



#### IV. FINDINGS AND OPINIONS

##### *“Descriptive/Explanatory Case Study” Method Employed by Dr. Perri*

20. Dr. Perri states that he used the “case method” to form his opinions in this case. He describes his work as a “descriptive/explanatory case study” in which he “review[ed] the documents and testimony provided to [him].”<sup>1</sup>
21. Dr. Perri did not use any scientifically valid methodology to form his opinions in this case; therefore, his subjective opinions are not scientifically valid. The “case method” is a pedagogical tool used, for example, in the classroom setting. It is not an accepted research methodology from which to draw conclusions from a set of facts. Dr. Perri cites no authority that recognizes the “case method” or a “descriptive/explanatory case study” as a scientifically valid research methodology, nor am I aware that any such authority exists.
22. Dr. Perri’s description of his work as a “descriptive/explanatory case study” confirms that the method he used lacks scientific rigor. Rather than arriving at a finding supported by research, Dr. Perri reviewed certain evidence provided to him and attempted to “describe” or “explain” his personal views of the evidence. This process does not constitute scientific research.
23. To the extent that Dr. Perri claims to have employed the “Case Study Research Methodology,” which is vastly different from a simple case study, he did not follow the accepted methods of the research design.
24. The “Case Study Research Methodology” is a seldom employed methodology that is utilized when preferred standard experimental design or quasi-experimental design are not possible. A leading publication acknowledges that “as a research endeavor, case studies have been viewed as a less desirable form of inquiry than other experiments or surveys.”<sup>2</sup> Because this type of research usually involves a single occurrence of an event, standard statistical comparisons between groups are not possible.
25. Because of the inherent nature of the design and data collection within standard case study methods, it is particularly important that these studies be properly designed and implemented with the utmost scientific rigor. If one fails to comply with standard methods, the study results are inherently unreliable.
26. The Case Study Research Methodology is commonly known to be susceptible to bias, meaning that the evaluator “has allowed equivocal evidence or biased views

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<sup>1</sup> Perri Report, ¶ 16.

<sup>2</sup> Robert K. Yin, *Case Study Research: Design and Methods*, 3d ed., p. 10.

to influence the directions of the findings and conclusions.”<sup>3</sup> If such bias is present, then the study results will be compromised.

27. The Case Study Research Methodology requires more than a researcher simply reviewing evidence and providing a subjective opinion regarding what that evidence means.
28. When properly employed to prevent such bias, any case study research that is intended to yield conclusions (*e.g.*, whether Abbott had a strategy of marketing the spread on its Ery products) should, prior to any data collection, include the following processes:
  - a. Identify the theoretical framework or underpinnings on which evidence will be evaluated.
  - b. Identify the research hypotheses or propositions, based on the above theoretical framework.
  - c. Identify the pattern of evidence that one would expect to see that would support or not support the research hypotheses or propositions.
  - d. Develop a protocol for data collection that identifies how data should be reviewed and coded, and how themes will be identified, categorized and analyzed.
29. It is my opinion that Dr. Perri did not utilize the Case Study Research Methodology in this analysis. Dr. Perri did not identify a theoretical framework for this research, did not identify hypotheses or propositions, did not a priori identify the patterns of evidence one would expect to see if Abbott had a strategy of marketing the spread on its Ery products, and did not provide a structured system of analysis for the data he reviewed.
30. Moreover, I have never seen the Case Study Research Methodology employed in the context of a lawsuit, a condition in which researchers themselves do not gather data or evidence via surveys, open-ended interview, or observations, but instead rely on evidence gathered and provided by lawyers in an adversarial proceeding.
31. Case Study Research Methodology also requires that investigators “attend to *all* the evidence, display and present the evidence separate from any interpretation, and show adequate concern for exploring alternative interpretations.”<sup>4</sup> (emphasis in original) In his report, Dr. Perri presents only the facts he believes support his opinion that Abbott’s strategy was one of marketing the spread, rather than providing objective evidence that either supports or does not support the issue in

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<sup>3</sup> Yin, p. 10.

<sup>4</sup> Yin, p. 109.

question. In the interpretation of the evidence he presents, he also does not address alternative or rival theories.

32. Due to the issues described above, Dr. Perri's conclusions regarding Abbott's corporate conduct, and its intentions, knowledge and perceptions, cannot be considered scientifically reliable or valid.

#### *Pharmaceutical Marketing and Marketing Theory*

33. Pharmaceutical companies are sophisticated businesses that utilize organized marketing efforts to support their products. Pharmaceutical marketing is well developed, systematic, and consistent. Corporate marketing decisions are not made in a simplistic or arbitrary fashion, but are part of a systematic process in which all marketing activities are consistent with a specific strategy for a product or product line.
34. Pharmaceutical marketing activities are typically presented in four distinct categories: 1) product, 2) promotion, 3) placement (distribution) and 4) price.<sup>5</sup> These categories are not specific to pharmaceutical marketing, but are standard in overall marketing theory. In the pharmaceutical industry, marketing activities in these four categories interact, complement each other, and are part of an overall marketing strategy for a particular product or product line.
35. For example, if a company had an overall marketing strategy to create value through being the "lowest cost, quality alternative," the marketing of that value would be consistent throughout each of the "Ps" of marketing. Setting the price lower than the alternative products alone would not suffice within this strategy. The product must be of similar or equal quality before this strategy could be employed. Distribution (placement) would have to be designed to make the product equally available as an alternative. As important, this message of the "low cost, quality alternative" would be consistently promoted to potential customers, typically through multiple promotion and advertising media.

#### *What "Marketing the Spread" Would Entail*

36. Dr. Perri, in his report, concludes that Abbott marketed the Ery products in question based upon the spread. I disagree that any such conclusion can be drawn from the evidence cited in Dr. Perri's report.
37. The idea of "marketing the spread" is akin to creating an overall product goal to maximize profits for providers through reimbursement by third parties. If a company employed a strategy to market the spread, product managers, sales representatives, and other company personnel responsible for marketing the product would incorporate that goal explicitly, and continuously into all the activities of the product. These activities would span all areas of marketing (*e.g.*,

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<sup>5</sup> Mickey C. Smith, *Pharmaceutical Marketing: Strategy and Cases*, 1<sup>st</sup> ed. (1991), p. 11-13.



the 4-Ps of marketing); therefore, one would expect to see consistent, explicit, systematic and continuous evidence that such a marketing plan were in place. Evidence of such a marketing strategy would exist in several forms, including internal discussions of the specific marketing plan, training materials explicitly outlining the goals and activities, research to determine if this plan was the appropriate course of action, and promotional materials to aid account representatives in presenting this explicit message to customers.

38. A strategy to market the spread, if implemented, would be communicated consistently and persistently throughout the company or relevant business unit. Because the process of marketing includes all four elements of price, product, placement, and promotion, an expert in pharmaceutical marketing would expect to see evidence of this overall strategy from multiple sources consistently over time in each of these discrete categories.
39. A marketing plan does not just “happen” at large pharmaceutical companies, and it is not dictated or defined by the isolated actions of individuals. The marketing strategies and resultant marketing plans are discussed, researched extensively, presented at internal meetings, then eventually (if approved) built in to a part of the overall product plan. Once approved, promotional messages are tested, promotional materials are created, representatives are trained, potential customers for the message are identified, and the message is delivered as planned. Throughout the process, there are constant feedback mechanisms and each component is evaluated for refinement or abandonment based on evolving market conditions or competitive response. Evidence of these activities would include (but not be limited to):
  - a. Consistent documentation as to how to best market the message of provider profitability.
  - b. Continuous process of building a product strategy and core message around the topic of marketing the spread.
  - c. Consistent and continuous research on the issue of provider profitability as a potential driver of sales.
  - d. Extensive and explicit research on the correct messages and materials to be used by representatives to promote the spread.
  - e. Evidence of continuous competitive intelligence research in the area of competitor pricing and “spread.”
  - f. Continuous internal training on how providers are compensated as a basis for making decisions on marketing the spread, including specific training on provider compensation by payer type and geographical region.
  - g. On-going and explicit development of training materials needed for marketing the spread.



40. Once past the planning stage and entering the implementation stage, companies must train their representatives as to how this message should be conveyed. That process would include both training personnel and developing the tools necessary for delivering the message. These activities would include (but not be limited to):
  - a. Explicit dissemination of the goal of maximizing provider reimbursement continuously over time.
  - b. Consistent use of this strategy as a metric for sales representative evaluation and performance goals.
  - c. Training materials for account representatives that are continuously revised for training existing and new hires. This information would include specific training for each sales representative and account managers on (at a minimum):
    - i. Regional and State differences in reimbursement and how that would affect the promotional message.
    - ii. How reimbursement has changed over time and how changes in promotion must change as a result.
  - d. Multiple versions of promotional materials including advertising pieces explaining to customers how Abbott products increased profits through maximizing reimbursement
  - e. Lectures, presentations, and internal training materials consistently and explicitly outlining the strategy of profit maximization for the provider as a goal of each sales presentation.
  - f. Internal correspondence and feedback as to the success of the strategy in the field—resulting in potential refining of the message
41. A strategy that focused on maximizing the spread for customers would drive all product pricing decisions as well. As such, one would expect to see consistent and continuous internal discussions of pricing actions, in the context of maximizing payer reimbursement. Pricing decisions based on this strategy would rely on extensive market research specifically designed to determine how to structure prices to maximize profitability based on the spread.
42. Based on the evidentiary material that Dr. Perri presented in his report, I disagree with his conclusion that Abbott had a strategy or plan to market its Ery products based upon the spread. The evidence simply does not reveal the type of continuous, systematic and explicit indicia of a marketing strategy as outlined above.

*Dr. Perri's Opinions Lack Supporting Evidence and Ignore Contrary Evidence*

43. Putting aside its methodological flaws and its lack of scientific rigor, Dr. Perri's report contains statements that are not supported by any evidence. For instance, in paragraph 50 of his report, Dr. Perri lists certain "marketing behaviors" that he has "noted" in this case, including "comparing Abbott and competitors' AWP prices, and in some cases profitability." However, Dr. Perri offers no evidence of Abbott doing this for any Ery product.
44. Dr. Perri's report also ignores substantial evidence that contradicts his opinions. For example, Dr. Perri states that Abbott marketed the spread for its Ery products by publishing a WAC with the understanding and intention that it would affect AWP and the spread. However, Joseph Fiske, Abbott's corporate representative, testified at his deposition that Abbott did not consider AWP or government payments when it adjusted the WAC for Ery products that Abbott submitted to pricing compendia. Fiske testified as follows:

"Q. When Abbott did that did it appreciate that in July of '99 or shortly thereafter its published AWP prices would also be increasing? A. I don't know that we ever took that into consideration. It's not something that we generally would have thought about. Q. Is there any reason why Abbott in July of '99 would not have understood that its AWPs would have gone up as a result of its increased WACs? A. No, but it's not something that we would have taken into consideration in terms of the price increase. It didn't influence our price increase in any way." "A. The WAC and list prices that we developed and reported were -- were, like I said, done so in good faith with no intent to influence reimbursement." Perri Dep, Ex. 9.

45. Although Dr. Perri states that he reviewed Mr. Fiske's deposition, he did not cite this particular testimony in his report, and did not address the rival theory that Mr. Fiske's testimony presents—namely that Abbott did not set or report its prices with any intention to influence government payments for Ery products. As stated, such selection bias and a failure to address rival theories negatively affect the reliability and validity of a researcher's conclusions.

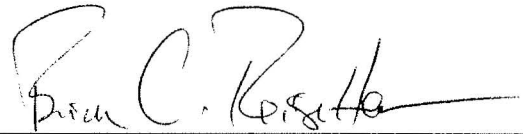
*Dr. Perri's Opinions are Inconsistent with Market Realities*

46. Dr. Perri suggests that Abbott reported inflated prices to the compendia in order to increase the spread on Abbott's Ery products over competitor spreads, and then marketed that spread as a reason for customers to choose Abbott Ery products over competitor products.
47. This finding assumes that any upward adjustment in Abbott's reported prices would in fact result in increased government payments for Abbott's Ery products over competitors. In reality, however, government payers imposed uniform

payment capitations, such as FULs and MACs, on all of Abbott's Ery products and their generically-equivalent competitors. Within this framework, the government would pay the same fixed amount for all Ery products (Abbott's or its competitors'), regardless of which generically-equivalent product was dispensed or which price Abbott or its competitors reported to the pricing compendia. If a FUL or MAC was in place, then Dr. Perri's finding that Abbott could, through increasing its reported prices, achieve for its customers a higher government payment level for its Ery products than for competitors' products would be spurious.

48. There were in fact FULs and/or MACs in place for these products for most of the time period after 1994.
49. At his deposition, Dr. Perri nonetheless claimed that Abbott still had a motivation to market the spread even though its Ery products have been subject to such FULs and MACs. He seems to claim that pharmacists would call physicians to approve the dispensing of an Abbott Ery product in place of a non-generically equivalent antibiotic that the physician actually prescribed, solely to receive a higher government payment.
50. In my extensive experience in the retail pharmacy setting, I have never encountered a program or strategy at any pharmacy whereby the pharmacy engaged in the practice outlined above. I have never employed such a practice myself, nor am I aware of any pharmacy that has done so. Furthermore, Dr. Perri cites no instance where he has observed such behavior, either.
51. I reserve the right to amend or supplement my opinions as new information is provided in this matter.

Dated: May 14, 2009

A handwritten signature in black ink, appearing to read "Brian C. Reisetter", written over a horizontal line.

Dr. Brian Reisetter



**Materials Considered by Dr. Brian C. Reisetter**

- 1) Complaint - United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., Civil Action No. 07-CV-11618, August 30, 2007
- 2) Report of Matthew Perri III, R.Ph.D., March 26, 2009, and evidence cited therein
- 3) Deposition transcripts of Dr. Matthew Perri, May 1, 2009 and May 7, 2009
- 4) Mickey C. Smith, *Pharmaceutical Marketing: Strategy and Cases*, 1st ed. (1991)
- 5) Robert K. Yin, *Case Study Research: Design and Methods*, 3d ed. (2002)
- 6) Fred N. Kerlinger, *Foundations of Behavioral Research*, 3d ed. (1986)

**Deposition Transcripts**

Deborah DeYoung 03/20/2007  
Beth Senger 12/17/2008  
Donna Arnold 12/18/2008  
Patricia Kadish 12/18/2008  
Russell Lehn 01/15/2009  
John Christopher Pavlik 01/22/2009  
Joseph Fiske (Volume I) 02/17/2009  
Joseph Fiske (Volume II) 02/18/2009  
Theresa "Tip" Parker 02/19/2009  
April Gerzel 02/20/2009

**Documents**

ABT 005762-80  
ABT 212051-5  
ABT\_ERY 00003564  
ABT\_ERY-E 00001087-91  
ABT\_ERY-E 00005000-4  
ABT\_ERY-E 00005954-65  
ABT\_ERY-E 00005976-88  
ABT\_ERY-E 00006011-32  
ABT\_ERY-E 00006043-63  
ABT\_ERY-E 00006305-26  
ABT\_ERY-E 00007713-67  
ABT\_ERY-E 00008987-9  
ABT\_ERY-E 00009458  
ABT\_ERY-E 00009460-62  
ABT\_ERY-E 00011616-7  
ABT\_ERY-E 00016521-4  
ABT\_ERY-E 00017027-30  
ABT\_ERY-E 00017188-205

ABT\_ERY-E 00018196-220  
ABT\_ERY-E 00018228-65  
ABT-DOJ 394762-5345  
ABT-DOJ 295979-7309  
ABT-DOJ 295990-2  
ABT-DOJ 295996  
ABT-DOJ 296200 and 295994  
ABT-DOJ-E 00002019-49  
ABT-DOJ-E 00586280-91  
ABT-ERY 00005638  
Certain State MAC lists  
CH 055666 and 055679  
CH 055666-55785  
Fiske 2/17/09 Exhibits 2, 3, and 4  
Omnicare 0000097-8  
Omnicare 0008643  
Pavlik Exhibits 17 and 18  
Red Book 00936-9  
TXABT 012280-315  
TXABT 015660-3  
TXABT 042077-8  
TXABT 060942-70  
TXABT 244823-43  
TXABT 244836-9  
TXABT 245236-7  
TXABT 269806-13  
TXABT 269964-70  
TXABT 270967-76  
TXABT 271911-8  
TXABT 325897-905  
TXABT 325908-11, 325906-7  
TXABT 325962-9  
TXABT 362108-13  
TXABT 362114-20  
TXABT 362114-20  
TXABT 370566-8  
TXABT 434310-3  
TXABT 453403-13  
TXABT 507188-202  
TXABT 507188-507202  
TXABT 672074-9  
TXABT 673723-673921  
TXABT 674625-6  
TXTABT-E 0033830  
TXTABT-E 0065053-67  
TXTABT-E 0251633-4  
VTP083-4880